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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|---------------------|------------------|
| 10/047,079 | 01/14/2002 | Meir Rosenberg | 022719-0026 | 5373 |
| 21125 | 7590 | 07/12/2005 | | |
| NUTTER MCCLENNEN & FISH LLP | | | EXAMINER | |
| WORLD TRADE CENTER WEST | | | | DEAK, LESLIE R |
| 155 SEAPORT BOULEVARD | | | ART UNIT | PAPER NUMBER |
| BOSTON, MA 02210-2604 | | | 3761 | |

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/047,079 | ROSENBERG ET AL. | |
| | Examiner | Art Unit | |
| | Leslie R. Deak | 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 May 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 3 and 5-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 3 and 5-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 14 January 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 3 and 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,141,502 to Macaluso, Jr. in view of 5,209,723 to Twardowski et al. Macaluso discloses a catheter with a proximal and distal end an inner lumen that extends between the proximal and distal ends (see FIG 7, 9). The distal end may comprise a coil-shaped region with between one and ten coils, between one and forty fluid entry ports thereupon, and a distal fluid port. The catheter is comprised of two sections: a distal tube body 19 and a bladder coil 23 that are connected at hub 27, wherein the tube portions are formed of polymeric material that retains its shape in a coiled position (see FIG 7, column 2, lines 1-5). With regard to applicant's omission of ports in a particular portion of the device, it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. See MPEP 2144.04. Macaluso discloses the device as claimed with the exception of the diameter of the coiled region being "substantially similar" to the diameter of the proximal portion of the catheter. Twardowski discloses a fluid flow catheter with a proximal and a distal end, the distal end in a helical shape that is slightly larger than the diameter of the catheter itself in order to prevent the openings

in the catheter from engaging the surrounding tissue. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to form the helical portion of the catheter into a shape that is substantially similar to the diameter of the proximal portion of the catheter in order to ensure a proper fit of the catheter into the designated space while still preventing the catheter's engagement with surrounding tissue. See also MPEP § 2144.04 regarding the matter of changes in size as obvious design choice. With regard to the size and shape of the fluid entry ports in the catheter, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges, such as size and shape in the instantly claimed invention, involves only routine skill in the art. See MPEP § 2144.05.

Response to Arguments

3. Applicant's arguments with respect to the rejection(s) of claim(s) 3, 5-8 under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new rejection has been made.
4. Applicant's arguments filed 25 May 2005 with regard to claims 19-20 have been fully considered but they are not persuasive. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 5,536,274 Neuss

i. Spiral implant for organ pathways with variable coil diameter

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


PATRICIA BIANCO
PRIMARY EXAMINER

7/8/05

Lrd

6 July 05